

MTBseq™

GeneMind NGS-based Solutions for Tuberculosis(TB) Genetic Detection and Drug-resistance Analysis

Accurate data performance

- Accurate characterization of nucleotide-level genetic polymorphisms
- Detailed sequence information for multiple gene regions or whole genome

Wide range of annotation

- Detection of resistance to a wide range of first and second-line anti-tuberculosis drugs
- Detection of mixed infection and identifying heteroresistance down to 3% of subpopulations

Automated workflow

- Automated and simplified sequencing and data analysis workflow
- Quick test from sample preparation to final report within 24 hours



◆ Background

Tuberculosis (TB) is an infectious disease caused by bacteria belonging to the *Mycobacterium tuberculosis* complex (MTBC), primarily *M. tuberculosis* (*M. tb*). The pathogen most commonly infects the lungs and is transmitted through airborne particles expelled by infected individuals. Globally, TB remains a major public health challenge. It ranks among the top ten causes of death worldwide, with 8.2 million new cases reported in 2023 and an estimated 1.23 million TB-related deaths in 2024.

M. tb's capacity to develop resistance to antimicrobial drugs poses a significant challenge to global diagnosis, treatment, and eradication initiatives. As *M. tb* continuously adapts, evolving mutations that confer resistance to new therapeutics, the demand grows for rapid and precise diagnostic tools to characterize these drug-resistance profiles.

《WHO consolidated guidelines on tuberculosis module 3 diagnosis》 provides recommendation that **tests based on targeted NGS offer great potential to provide comprehensive resistance detection matched to modern treatment regimens.**

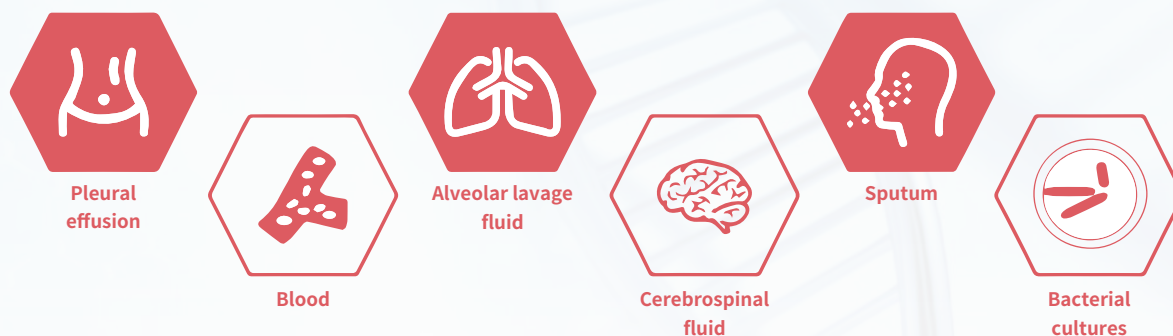
◆ Product Introduction

Based on tNGS (targeted next-generation sequencing) technology and NGS platforms (FASTASeq™ S, FASTASeq™ 300, and SURFSeq™ 5000), GeneMind has launched a fully automated end-to-end solution of TB drug resistance detection product-MTBseq™. This solution can directly test sputum and other samples of patients quickly and accurately, without cell culture process. It helps to speed up the early detection of infectious sources, diagnosis of tuberculosis, know TB drug resistance and provide the guide for clinical treatment.

◆ Drug Resistance Gene List

Drug Resistance Gene List		
	Drug type	Gene list
First-line anti-tuberculosis drugs (4)	Rifampicin	<i>rpoB</i>
	Isoniazid	<i>fabG1, katG</i>
	Ethambutol	<i>embB</i>
	Pyrazinamide	<i>pncA</i>
Second-line anti-tuberculosis drugs (8)	Streptomycin	<i>rpsL, gid</i>
	Ethionamide	<i>ethA, fabG1, inhA</i>
	Para-aminosalicylic acid	<i>folC, ribD, thyA</i>
	Levofloxacin	<i>gyrA, gyrB</i>
	Cycloserine	<i>alr</i>
	Kanamycin	<i>eis</i>
	Amikacin	<i>eis</i>
	Fluoroquinolones	<i>gyrA, gyrB</i>
Novel anti-tuberculosis drugs (5)	Delamanid	<i>gbiA</i>
	Bedaquiline	<i>Rv0678</i>
	Linezolid	<i>rplC</i>
	Capreomycin	<i>tlyA</i>
	Moxifloxacin	<i>gyrB</i>

◆ Sample Type



Parameter			
Sample volume	≥0.5 mL		
Library preparation	multiplex PCR		
Method	Targeted sequencing		
Sequencing platform	FASTASeq™ S	FASTASeq™ 300	SURFSeq™ 5000
Number of samples/run	1 FCL: 8 1 FCM: 18	1 FCH: 96 1 FCP: 192	1 FCM: 192 1 FCH: 768
Turnaround time*	12.8/13.8 h	26.5/49 h	43/114 h
Sequencing strategy	PE100, ≥2 M raw reads per sample		
Report generation	Local analysis and report system		

*The calculation based on the automated workflow requires adjusting the specific time according to the sample number and is also related to the proficiency level of the personnel in each laboratory.

◆ Automated Workflow-96 samples



◆ Data Performance-606 cases

Rifampicin	DST	
	+	-
MTBseq™	51	9
	1	149
Sensitivity	98.08% (CI 89.88%-99.66%)	
Specificity	94.30% (CI 89.53%-96.97%)	

Isoniazid	DST	
	+	-
MTBseq™	58	2
	6	118
Sensitivity	90.63% (CI 81.02%-95.63%)	
Specificity	98.33% (CI 94.13%-99.54%)	

Ethambutol	DST	
	+	-
MTBseq™	26	4
	3	151
Sensitivity	89.66% (CI 73.61%-96.42%)	
Specificity	97.42% (CI 93.55%-98.99%)	

Fluoroquinolones	DST	
	+	-
MTBseq™	14	0
	2	12
Sensitivity	87.50% (CI 63.98%-96.50%)	
Specificity	100% (CI 75.75%-100%)	

The clinical samples were compared using MTBseq™ and DST (Phenotypic Drug Susceptibility Testing) for four common drugs, and both sensitivity and specificity were relatively high.

◆ Application: Clinical Sample

Conclusion: Data from Figures 1 and 2 demonstrate that tNGS is more sensitive and accurate than traditional qPCR for TB drug resistance detection, as it identified resistance genes by day 8, while DST (MIC testing) only indicated resistance by day 12.

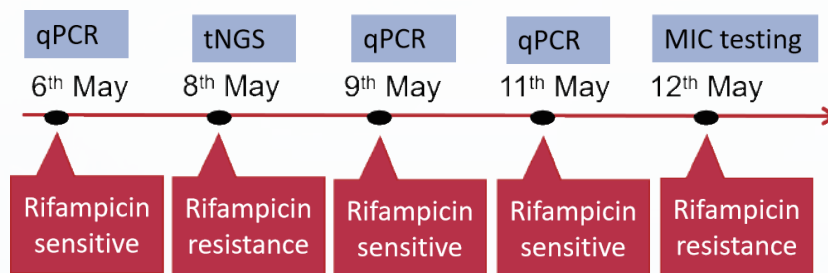


Figure 1 Detection timeline of the clinical sample

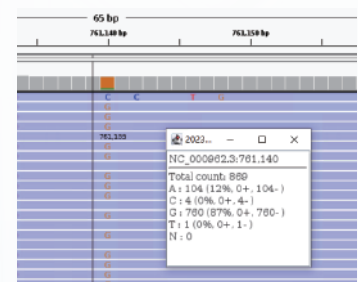


Figure 2 MTBseq™ testing result

✂ Disclaimer

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